SEP 1 8 2000

K002540

Summary of 510(k) Premarket Notification

(a)(1) Submitter's name, address and contact:

Bionostics, Inc.
2 Craig Road
Acton, MA 01720

Contact: Kathleen Storro
Director Quality Assurance and Regulatory Affairs
Telephone No.: 978-263-3856, ext. 220
E-mail: kstorro@bionosticsinc.com

Date Summary Prepared: 08-15-00

(a)(2) Device trade name:

Bionostics Glucose Quality Controls for Medisense Blood Glucose Test Systems

Classification Name: Single Analyte Controls (Assayed and Unassayed)
Classification Number and Class: 75JJX, Class I

(a)(3) Substantial Equivalence

The Bionostics Glucose Controls in Five Levels for Medisense Blood Glucose Test Systems is substantially equivalent in function, safety and efficacy to two products currently being marketed:

a. LifeScan's SureStep® Pro Linearity Solution (LifeScan Inc., Milpitas, CA 95035); and
b. Sugar-Chex® Linearity (Streck Laboratories Inc. 14124 Industrial Road, Omaha, NE 68144).

This 510(k) submission contains information to show substantial equivalence with these products.

(a)(4) Description of the New Device

The Bionostics Glucose Quality Control Solution is a non-hazardous aqueous glucose control solution. The control contains no human-based materials.

The Bionostics Glucose Quality Control Solution product is packaged in plastic bottles, which have dropper tips for application of the solution to test strips. The control has a red color to help users see the solution when dispensing it onto a test strip.

(a)(5) Intended Use:

These glucose control solutions are to verify the performance of certain Medisense Blood Glucose Test Systems at the upper and lower ends of the reportable range and at three points within the range. The Controls can therefore be used to:

(i) assess the linearity and calibration of the test system; and
(ii) verify system performance.

For in-vitro diagnostic use.

(a)(6) Technical Characteristics of the Device

This material consists of aqueous glucose control solutions prepared in five specific glucose concentrations. The solutions have been formulated to simulate the reaction of whole human blood when used with Medisense Blood Glucose Test Systems.

The product contains no human-based materials. No significant changes in properties or performance occur when the solutions are stored at room temperature for at least two (2) years.

(b)(1)(2) Summary of performance testing submitted with the premarket notification:

Tests were conducted to verify two performance requirements:

a. accurate measurements of glucose expected values; and

b. test precision, which is suitable for monitoring the performance and linearity of the test glucose test systems.

(b)(3) Conclusions from tests of the device:

Tests verify that Bionostics Glucose Control provides test response and precision, which will serve as an important adjunct to the laboratory's quality control program for Medisense Blood Glucose Test Systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 1 8 2000

Ms. Kathleen Storro
Director QA/RA
Bionostics
2 Craig Road
Acton, Massachusetts 01720-5405

Re: K002540
Trade Name: Bionostics Glucose Controls in Five Levels for Medisense Blood Glucose Test Systems
Regulatory Class: I
Product Code: JJX
Dated: September 11, 2000
Received: September 13, 2000

Dear Ms. Storro:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number: K002540 (not yet assigned)

INDICATIONS FOR USE:

Device Name: Bionostics Glucose Controls in Five Levels for Medisense Blood Glucose Test Systems

A. INDICATIONS FOR USE:

Bionostics Glucose Controls in Five Levels are to verify the performance of Medisense Blood Glucose Test Systems at the upper and lower ends of the reportable range and at three points within the range. The Controls can therefore be used to:

(i) assess the linearity and calibration of the test system, and
(ii) verify system performance.

This product is intended for professional use only.

This product is for in-vitro diagnostic use only.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K002540

V Rx

Revised: 09/11/00